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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,587	07/10/2002	Leszek Wojnowski	VOS-30	7615

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EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,587	WOJNOWSKI ET AL.	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-8, 12-13, 37 and 39-40 in part, as specifically drawn to the special technical feature of a polynucleotide, vector, host cell and primer.
(Upon election of Group 1, the applicant must choose ONE nucleic acid SEQ ID NO from Claim 1, as each SEQ ID NO is a distinct invention requiring separate searches, NOT a species)

Group 2, claim(s) 9 and 39-40 in part, as specifically drawn to the special technical feature of a CYP3A4 or CYP3A7 polypeptide.
(Upon election of Group 2, the applicant must choose ONE amino acid SEQ ID NO from Claim 1, as each SEQ ID NO is a distinct invention requiring separate searches, NOT a species)

Group 3, claim(s) 10-11 and 39-40 in part, as specifically drawn to the special technical feature of an antibody.
(Upon election of Group 3, the applicant must choose ONE amino acid SEQ ID NO from Claim 1, as each SEQ ID NO is a distinct invention requiring separate searches, NOT a species)

Group 4, claim(s) 14-16, as specifically drawn to the special technical feature of transgenic non-human animal.
(Upon election of Group 4, the applicant must choose ONE nucleic acid SEQ ID NO from Claim 1, as each SEQ ID NO is a distinct invention requiring separate searches, NOT a species)

Group 4, claim(s) 17-18, 21-23 and 34-36, as specifically drawn to the special technical feature of a method of identifying and obtaining a CYP3A4 or CYP3A7 inhibitor by contacting a cell expressing a molecular variant CYP3A4 or CYP3A7 gene.

Group 5, claim(s) 19-22, as specifically drawn to the special technical feature of a method of identifying and obtaining a CYP3A4 or CYP3A7 inhibitor by contacting a protein.

Group 6, claim(s) 24 in part, 25-28 and 34-36, as specifically drawn to the special technical feature of a method of diagnosing a disorder related to the presence of a molecular variant of the CYP3A4 or CYP3A7 gene comprising determining the presence of a polynucleotide.

Group 7, claim(s) 24 in part, 25-27, as specifically drawn to the special technical feature of a method of diagnosing a disorder related to the presence of a molecular variant of the CYP3A4 or CYP3A7 gene comprising determining the presence of a protein.

Group 8, claim(s) 29-31, as specifically drawn to the special technical feature of a method for the production, i.e. synthesis, of a pharmaceutical composition.

Group 9, claim(s) 32-33 and 39-40 in part, as specifically drawn to the special technical feature of an inhibitor.

Group 10, claim(s) 28, as specifically drawn to the use of an antibody capable of binding specifically to the gene product of a CYP3A4 or XYP3A7 gene.

The inventions listed as Groups 1-10 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups 1-10 appears to be nucleic acid molecules that encode molecular variants of cytochrome CYP3A4 or CYP3A7.

However, Westlind *et al.* (IDS, 1999) describes the evaluation of testosterone hydrolase activity of CYP3A4 from 46 different human liver samples, which leads to the identification of three nucleotide exchanges, all causing a mutation of A to G at –290 (CYP3A4-V) in the nifedipine specific element: the importance of this polymorphism was evaluated. In addition, Lichter (IDS, 1999) teaches a method for detecting polymorphism in CYP3A4 in an individual (pages 15 to 17, lines 29-24, respectively, Table 3). The presence of the predisposing polymorphism is indicative of an alteration in CYP3A4 expression or activity. The method is useful to screen patients for altered metabolism of CYP3A4 substrates, potential drug-drug interactions and adverse side-effects and diseases that result from environmental or occupational exposure to toxins; the variant nucleic acids may be used to establish animal, cellular and in vitro cell-fee models of drug metabolism.

Therefore, the technical feature linking the inventions of Groups 1-10 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claim 22, Group 4 and 5, is generic to a plurality of disclosed patentably distinct species comprising the following molecules: nifedipine, rifampicine or corticosterone which differ at least in chemical structure, and mechanism.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

GARY NICKOL
PRIMARY EXAMINER